K092949

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:

August 21, 2009

Submitter's Information: 21 CFR 807.92(a)(1)

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OCT - 8 2009

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	ImageGrid Radiology Viewer System™
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050 System, Image Processing
Product Code:	LLZ

Predicate Device: 21 CFR 807. 92(a)(3)

510(k) Number:	K080333	K031311
Manufacturer:	CANDELIS, INC.	DYNAMIC IMAGING, INC.
Device Name:	IMAGEGRID	INTEGRADWEB
Decision Date	02/22/2008	06/20/2003
Product Code:	LLZ	LLZ
Device Classification Name:	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL
Regulation Number:	Class II - 892.2050	Class II - 892.2050
Reviewed by Third Party	Yes	No

Device Description: 21 CFR 807 92(a)(4)

ImageGrid Radiology Viewer System™ is a client/server software application that is designed to be used with the ImageGrid PACS device or as an independent service. The ImageGrid Radiology Viewer System™ can query, retrieve, and display medical images that it retrieves from a DICOM SCP. The device is a client/server software service that permits concurrent access to the ImageGrid PACS' medical images.

Indications for Use: 21 CFR 807 92(a)(5)

ImageGrid Radiology Viewer System™ is a device that receives medical images and data from various imaging sources. Images and data can be stored, communicated, and displayed within the system or across computer networks at

distributed locations. Only pre-processed DICOM for presentation images can be interpreted for primary image diagnosis in mammography. Lossy compressed Mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA. Diagnosis is not performed by the software but by Radiologists, Clinicians and referring Physicians as an adjunctive to standard radiology practices for diagnosis. Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, medical technicians, and assistants.

Technological Characteristics: 21 CFR 807 92(a)(6)

ImageGrid Radiology Viewer System™ device is a software product that handles digital medical images. The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Testing

The complete system configuration has been assessed and tested at the factory and the device has passed all in-house testing criteria without significant failures. The data presented in the submission demonstrates that the ImageGrid Radiology Viewer System performs all required actions according to the functional requirements specified in the SRS and User Manual with no errors that had an impact on safety or efficacy.

Conclusion: 21 CFR 807 92(b)(1)

The 510 (k) Pre-Market Notification for ImageGrid Radiology Viewer System™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. ImageGrid Radiology Viewer System™ has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the "Level of Concern for potential hazards has been classified as "Moderate".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT - 8 2009

Candelis, Inc.
% Mr. Ned Devine
Senior Staff Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Rd.
NORTHBROOK IL 60062

Re: K092949
Trade/Device Name: ImageGrid Radiology Viewer System
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: September 22, 2009
Received: September 24, 2009

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K092949

Device Name: ImageGrid Radiology Viewer System™

Indications for Use:

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Diagnosis is not performed by the software but by Radiologists, Clinicians and referring Physicians as an adjunctive to standard radiology practices for diagnosis. Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, medical technicians, and assistants.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092949